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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/729,343 10/16/96 LEE

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HM12/0419

EXAMINER

KULKOSKY, P

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

04/19/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

## Office Action Summary

Application No.

08/729343

Applicant(s)

Doruk D. Lee et al

Examiner

P. Kulkarny

Group Art Unit

1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 1 - 3, 5, 7, 9-16, 21 - 26 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1 - 3, 5, 7, 9-16, 21 - 26 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

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Claims 1-3, 5, 7, 9-16, 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/04657 or Constantz 4,880,610 or WO 94/02412 each taken alone or in view of Fukase et al and Rey Abstract.

The applicants' arguments are not convincing that the cited Prior Art is not enabling for preparation of a cement paste of the instant claims. The claims may include and have not been experimentally demonstrated to exclude the poorly crystalline calcium phosphate and "acidic second calcium phosphate" which are among the most routinely utilized materials for such bone cement applications. The cited Prior Art details characteristics of calcium phosphate starting materials and points out setting times (see Y. Fukase et al Article). The applicants' arguments are moot in regard to unexpected results of a particular poorly crystalline amorphous calcium phosphate since there are no limitations to express improved setting times, compressive strength or other working properties. If the process of example 1 of the instant specification yields a paste or set cement of improved properties, it is not clear that the claims define such an effect.

In view of the close similarity and approximate identity of the calcium phosphates of the instant claims and those of the cited Prior Art, it is incumbent upon the Applicants to provide comparisons with the closest examples of calcium phosphate applications in the cited Prior Art (see In re Best 195 U.S.P.Q. 430).

The Cited Prior Art patents and publications are not necessarily limited to in vivo or in vitro applications since those skilled in the art are presumed to be enabled to use the disclosed calcium phosphate cements surgically, absent expert testimony to the contrary.

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There is no convincing evidence of record that the claims are reciting new materials or anything which would be reported scientifically as physically different from amorphous calcium phosphates which are commercially available or preparable by following the procedures of Constantz or of the WO Prior Art. A method of treating a bone defect cannot be considered to be improved in comparison with the Prior Art similar calcium phosphate cement as the claims do not contain limitations "due to the use of said species" of poorly crystalline calcium phosphate.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Kulkosky:mv

April 5, 2001



PETER F. KULKOSKY  
PRIMARY EXAMINER